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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,826	01/04/2001	Mohamed E. El Halawani	600.492US1	3468

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/754,826	EL HALAWANI ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8 and 29* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/29/04 has been entered.

Claims 1-3, 5-8 and 29 are pending.

Claims 1-3, 5-8 and 29 are under consideration in the instant application.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection**.

" The immunoconjugate of claim 1 wherein the peptide is glutathione-S- transferase" claimed in claim 29 represent a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for the" peptide is glutathione-S- transferase". The specification and the claims as originally field only support fusion polypeptide, wherein non-myostation portion of the fusion polypeptide is a histidine tagged, as disclosed in the Specification as filed on page 30 , lines 5-10.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claim 1-2 , 6-8 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al.(US. Pat. No. 6,369,201, see entire document) for the same reasons set forth in the previous Office Action, mailed 09/23/03

Applicant's arguments, filed 02/29/04 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) Barker et al. do not teach or suggest claimed immunoconjugate, because the body weights for the group treated with a recombinant myostatin immunoconjugate were not significantly different from the body weights in control groups i.e. the reconstituted myostatin immunoconjugate did not elicit an immune response; (ii) Barker et al., only describes ten myostatin oligonucleotides to be employed in a reconstructed myostatin sequences .

Contrary to Applicant's assertion Barker et al. teach mature forms of vertebrate myostatin polypeptide and myostatin immunoconjugate comprising at least one myostatin polypeptide linked to an immunological carrier . (see entire document, colum 3, lines 25-40, Column 4, especially lines 1-4; column 7 lines 15-22, column 9, lines 22-35). In Detailed Description, Barker et al. teach that the term "myostatin immunogen" includes polypeptide of myostatin molecule, which elicits an immunological response (see column 6, lines14-25, column 15 lines 1-5, and column 16, lines 42-45). In addition, Barker et al., explicitly teach that administration of a myostatin immunoconjugate results in an increase in body weight (see column 4, lines 15-35 in particular). Moreover, Applicant himself acknowledge that , Barker et al. disclosed a myostatin immunoconjugates capable of eliciting an immune response in a vertebrate subject (see page 4of Applicant's arguments, 12/29/03 in particular). Barker et al. also teach vaccine composition comprising the myostatin polypeptide and pharmaceutically acceptable excipient (Column 4, line 10-15). In Detailed Description, Barker et al. teach that myostatin molecule is administrated in the mix with a pharmaceutically acceptable excipient, such as water, saline, dextrose , glycerol, ethanol. (Column 23, lines 45-65).

Barker et al. also teach that to enhance immunogenicity of myostatin, myostatin immunoconjugate which comprises a fusion polypeptide can be used. (see Detailed Description, Column 10, lines 5-10).

With regards to Applicant's arguments that Barker et al., only describes ten myostatin oligonucleotides to be employed .

Contrary to Applicant's assertion , Barker et al. also teach myostatin peptides consisting about 3 to about 200 amino acids, or consisting a mature form of myostatin spanning from amino acid 1 through 350 that are derived from various vertebrate species, including turkey myostatin (see column 3, lines 25-45 and Fig.1A-1D). In column 4, line 55, Barker et al. teach turkey myostatin (SEQ ID No: 35) that comprises SEQ ID NO :2 of the instant claim 3.

Claim 29 is included because the term "optionally" is interpreted as if the claimed myostation immunoconjugate does not contains a peptide useful for purification or identification.

The reference teaching anticipates the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-2 , 5- 8 and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al.(US. Pat. No. 6,369,201) in view of Harris et al. (Micron 1999, 30, 597-623) for the same reasons set forth in the previous Office Action, mailed 09/23/03

Applicant's arguments, filed 02/29/04 have been fully considered, but have not been found convincing.

Applicant asserts neither Barker et al. nor Harris et al. disclosed or suggest a myostatin immunoconjugate, comprising the mature form of vertebrate myostatin linked to the carrier.

Contrary to Applicant's assertion, as was discussed above, it is the Examiner position that Barker et al. teach mature forms of vertebrate myostatin polypeptide and myostatin immunoconjugate comprising at least one myostatin polypeptide linked to an immunological carrier . (see entire document, column 3, lines 25-40, Column 4, especially lines 1-4; column 7 lines 15-22, column 9, lines 22-35). Berker at al. further teach that immunological carrier can be any molecule which, when associated with a myostatin immunogen, enhances the immunogenicity of the molecule. (Column 9, lines 22-34).

Barker et al. do not explicitly teach that the carrier is KLH.

However, Harris et al. teach the widespread use of KLH as a hapten carrier and generalized vaccine component that is widely used to enhances the immunogenicity of the vaccine (see Abstract and entire document).

Given the teaching of Harris et al. that KLH is widely used as a carrier to enhance the immunogenicity of the vaccine, one of ordinary skill in the art would have find it obvious to modify the teaching of Barker et al. and substitute carrier described by Barker et al. for KLH carrier to enhances the immunogenicity of myostatin immunoconjugate. One of ordinary skill in the art at the time the invention was made would be motivated to substitute immunological carrier, described by Barker et al. for KLH carrier to enhances the immunogenicity of myostatin immunoconjugate. Finally, given the art recognize widespread use of KLH as a carrier to enhance the immunogenicity, one ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to generate a myostatin immunoconjugate, comprising a myostatin polypeptide linked to KLH as a carrier.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. No claim is allowed.

8. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 21, 2004.

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